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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/071,541	05/04/1998	H.-J. SU HUANG	040750-5001	5607

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EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 11/26/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/071,541

Applicant(s)

HUANG ET AL.

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is no support seen for "an amount of a tyrosine kinase inhibitor that is synergistically effective" in accordance with claims 1, 9, and 13. The Examiner has reviewed the passages of the specification cited by Applicant in the first paragraph on page 3 of the response of 11-14-02. The Examiner accepts that synergistic amounts are described for AG1478 and AG1517 when employed *in vitro* under the conditions stated. However, there does not appear to be an adequate description of the intended amount of any other

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tyrosine kinase inhibitor, or of AG1478 and AG1517 when employed either *in vivo* or *in vitro* under different conditions.

Claims 1-7 are again rejected, as set forth in the Office actions of 06-06-01 and 12-14-01, under 35 U.S.C. 102(a) as being anticipated by NAGANE *et al.* (C24).

Applicant's statement in the response of 11-14-02 that a declaration will be submitted to address this rejection is noted.

Claims 1-16 are again rejected, as set forth in the Office action 12-14-01, under 35 U.S.C. 103(a) as being unpatentable over HAN *et al.* (K) in view of REED (A), further in view of TSAI *et al.* (aa).

Applicant's arguments filed 11-14-02 have been fully considered but they are not persuasive.

Applicant argues that there would have been no motivation to combine the teachings of the references. The Examiner does not agree. Applicant states that TSAI does not concern a mutant EGFR gene. The statement is correct, but does not detract from the Examiner's position. The mutant EGFR gene, as well as inhibition of cells expressing it by tyrphostin AG1478, is taught by HAN, as stated in the Office action 12-14-01. TSAI is

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relied on, also as stated in the Office action 12-14-01, to teach that a selective tyrosine kinase inhibitor is able to enhance the sensitivity of certain cancer cells to chemotherapeutic agents doxorubicin, etoposide, and cis-diamminedichloroplatinum(II) (cisplatin). Thus, the motivation to combine the teaching of HAN with that of REED concerning induction of apoptosis by cisplatin, taxol, and vincristine is provided by TSAI. In view of the teaching of TSAI concerning the ability of a selective tyrosine kinase inhibitor to enhance the sensitivity of certain cancer cells to chemotherapeutic agents, an ordinarily skilled worker would have expected the claimed combination therapy to result in modulation of the apoptosis-inhibiting effect of Δ EGFR, in accordance with the instant method claims. It is not necessary to the Examiner's *prima facie* case that any of the references disclose that a mutant EGFR gene is involved in modulation of apoptosis in a tumor cell, but only that the references reasonably would have suggested to one ordinarily skilled in the art to do what Applicant now claims.

Applicant continues to argue that the references do not teach the amount of tyrosine kinase inhibitor required by the claims. It remains the Examiner's position that this argument is not persuasive because the amounts taught or suggested by the

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references are those which would meet the claim limitations.

The Examiner especially notes page 18, lines 13-15 of the specification, which states with regard to tyrosine kinase inhibitors that "[s]uch agents also can be administered in dosages known to be effective or that can readily be determined as effective by one skilled in the art." Given this description of Applicant's invention, and in the absence of any more specific indication of what is meant by "an amount of a tyrosine kinase inhibitor that is synergistically effective" in accordance with the claims, the Examiner concludes that the amounts taught or suggested by the references are within the scope of the claims.

No claim is allowed.

This is a request for continued examination of applicant's earlier Application No. 09/071,541. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b).

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Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

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INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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